Nos. 95-754 & 95-886

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Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.,

Petitioner/Cross-Respondent,

v.

LORA LOHR AND MICHAEL LOHR,

Respondents/Cross-Petitioners.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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BRIEF OF *AMICUS CURIAE* GENERAL MOTORS CORPORATION IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act expressly preempts state common law claims that would expose a manufacturer to liability for marketing a medical device design that the Food and Drug Administration reviewed and affirmatively authorized for marketing under the Act's complex regulatory scheme.

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BRIEF OF AMICUS CURIAE GENERAL MOTORS CORPORATION IN SUPPORT OF PETITIONER

INTEREST OF *AMICUS CURIAE*

General Motors Corporation ("General Motors") is the world's largest manufacturer of automobiles.[1]

Prior to 1966, the American automobile industry was regulated primarily by an uneven combination of state common

[1] Pursuant to Rule 37.3(a) of this Court, both petitioner and respondents have consented to General Motors Corporation's filing of this brief as *amicus curiae*. Letters evidencing such consent are on file in the Clerk's office.

law and state legislative enactments that differed widely from one state to another. Often the courts led the way by developing and applying common law principles. These substantive principles, in turn, were sometimes later codified or revised by the state legislatures when they took the initiative to resolve particular problems with the common law or address particular concerns. The result was a haphazard patchwork of state-law regulation of the automobile under the common law and under statutory and regulatory provisions.

In 1966, however, Congress determined that, given the "centralized, mass production, high volume character of the motor vehicle manufacturing industry in the United States," the country needed "strong and adequately enforced" federal motor vehicle safety standards that were "*uniform* throughout the country." S. Rep. No. 1301, 89th Cong., 2d Sess. 12, *reprinted in* 1966 U.S. Code Cong. & Ad. News 2709, 2720 (emphasis added); *see* H.R. Rep. No. 1776, 89th Cong., 2d Sess. 17 (1966). Accordingly, Congress enacted the National Traffic and Motor Vehicle Safety Act of 1966, Pub. L. No. 89-563, 80 Stat. 718 (1966), 49 U.S.C. §§ 30101-30169 (the "Safety Act"), which directed the Department of Transportation, through the National Highway Traffic Safety Administration ("NHTSA"), to develop and issue federal motor vehicle safety standards that are "practicable," "meet the need for motor vehicle safety," and apply uniformly throughout the country. 49 U.S.C. § 30111(a).

The structure of the preemption provisions in the Safety Act is similar (though not identical) to those in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301-395 (the "FDCA"), the statute under review in this case. Specifically, the Safety Act contains an express preemption clause that provides:

> When a motor vehicle safety standard is in effect under this chapter, a State or a political subdivision of a State may prescribe or continue in effect a standard applicable to the same aspect of performance of a motor vehicle or

> motor vehicle equipment only if the standard is identical to the standard prescribed under this chapter. 49 U.S.C. § 30103(b)(1).

Moreover, similar to the FDCA, the Safety Act also contains what has sometimes been referred to as a "savings" clause. That provision states as follows:

> Compliance with a motor vehicle safety standard prescribed under this chapter does not exempt a person from liability at common law. 49 U.S.C. § 30103(e).

The similarity in structure of the statutory provisions concerning preemption contained in the FDCA and the Safety Act, *compare infra* at 4-5, makes the resolution of certain issues in this case potentially relevant to similar issues that have arisen under the Safety Act. In particular, *amicus* General Motors has an interest in the resolution of two questions that have arisen in this case, which we address here: *First*, does an express preemption provision that broadly preempts any different state-law "requirement[s]" (the FDCA) or "standard[s]" (the Safety Act) preempt state common law damages actions that would, if allowed, set requirements or standards that differ from the applicable federal requirements or standards? *Second*, does the mere inclusion by Congress of a so-called "savings clause" for common law liability afford state common law damages actions a *blanket* exemption from an express preemption provision that, by its plain terms, covers the state common law?

As the resolution of these questions in the context of the FDCA is relevant to litigation under the Safety Act, General Motors has an interest in the Court's analysis and resolution of the issues presented in this case.[2]

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[1] We note that the case before the Court has been litigated solely on grounds of express preemption, *see* Pet. App. 10a n.5, and accordingly any

(continued...)

INTRODUCTION

The FDCA contains two provisions that are most germane to the preemption issues presented in this case.

First, the FDCA contains an "express preemption clause," 21 U.S.C. § 360k(a), which states as follows:

> Except as provided in subsection (b) of this section [not relevant here], no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Second, the FDCA also contains a so-called "savings clause," 21 U.S.C. § 360h(d), which states as follows:

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action

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[2](...continued)
determination of implied conflict preemption under the FDCA and its implementing regulations is not at issue at this juncture. As under the Safety Act, however, implied conflict preemption will arise in appropriate cases as the courts confront state common law claims that directly conflict with the statutory and regulatory scheme. *See, e.g.*, Medtronic Br. at 46 n.24; Lohrs' Br. at 23 n.6.

> of any remedy provided him under such order shall be taken into account.

This provision is found in Subchapter V of the FDCA, which specifically applies to drugs and medical devices.

A harmonious and sensible construction of these two provisions goes a long way toward resolving the preemption issues raised in this case, and is also relevant generally to basic preemption issues that arise under a number of other federal regulatory statutes, including the Safety Act.

In harmonizing these provisions, the Court of Appeals made four determinations that are germane to the issues addressed by *amicus* General Motors:

First, the Court of Appeals held that reference in section 360k(a), the express preemption clause, to state "requirement[s]" covered not only state statutory law and administrative regulations, but also requirements that are imposed by state common law damages actions. Pet. 11a.

Second, it held that the existence of the so-called "savings clause" in the FDCA did not alter its conclusion that section 360k(a) covered "requirement[s]" imposed by common law damages actions, because the savings clause could be construed in any of several different ways without concluding that it was intended to exempt *all* common law damages actions from the preemptive force of section 360k(a), and that in any event a general savings clause "cannot supersede the specific preemption provision." Pet. 12a.

Third, the Court of Appeals therefore held that whether specific state requirements or standards were preempted under the FDCA demanded "a claim-by-claim inquiry" into whether each individual state claim would impose requirements that "are 'different from or in addition to' and 'relate to any matter' included in a specific [federal] requirement." Pet. 22a-23a (quoting 21 U.S.C. § 360k(a)).

Finally, the Court of Appeals held that its claim-by-claim preemption analysis must be guided by "the presumptions against preemption," and that "in a close case the presumptions tip our statutory interpretation against preemption." Pet. 9a.

Amicus General Motors respectfully submits that each of these conclusions, *except the last one* (concerning the purported presumptions against preemption) is correct, and, for the reasons addressed here, the Court should so hold in deciding this case.

SUMMARY OF ARGUMENT

1. The express preemption clause in the FDCA -- section 360k(a) -- prohibits each state from establishing or continuing in effect any requirement that is different from, or in addition to, any FDCA "requirement" that applies to the same medical device, and that relates to its safety, effectiveness, or any other matter governed by federal law. The Lohrs argue that state common law damages actions enjoy a *blanket* immunity from case-by-case preemption analysis because state common law is not a "requirement" within the meaning of section 360k(a).

The Lohrs' argument is plainly wrong for a number of reasons. First, the Court has already rejected their argument in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), holding that a term in an express preemption clause such as "requirement[s]" sweeps broadly and easily encompasses state common law. Second, even if the issue were not foreclosed, the Lohrs' argument ignores that state common law can set "requirements" regulating private conduct as much as state positive law. Third, the Lohrs' argument rests on the bizarre assumption that Congress intended that a single state jury -- an *ad hoc* collection of citizens assembled to hear one case -- should have more power to regulate private conduct in a manner different from the federal government than a state's duly elected and appointed officials. Moreover, the Lohrs'

contorted linguistic argument why "requirement[s]" does not cover state common law, if accepted, would undermine cases as basic as *Erie R.R. v. Tompkins*, 304 U.S. 64 (1938).

2. The Court should also reject the Lohrs' extreme position that the mere existence of a so-called general "savings" clause in a federal statute demonstrates that the common law is beyond the reach of an express preemption provision which would otherwise cover the common law. The Court has expressly held in prior cases that a general savings clause cannot control the obvious thrust of an express preemption clause. Indeed, the most sensible reading of the savings clause is as a general admonition that the mere enactment of the federal statutory scheme should not be understood to "occupy the field" so as to displace any and all state regulation at the outset of the regulatory regime. Under such a reading, state common law is neither completely displaced, nor completely immunized from express preemption. Instead, determination of the extent to which state common law is expressly preempted must proceed on a claim-by-claim basis, and will depend in large part on the nature of the federal regulations and standards that are established through the regulatory process. That is precisely what the Court of Appeals correctly held in this case.

3. Finally, in conducting its claim-by-claim determination of whether the Lohrs' common law claims are preempted, the Court of Appeals erred in relying on a so-called "presumption against preemption" as a means of tipping the balance in a close case. This Court's prior statements concerning a presumption against preemption are best understood as limited to cases where it is claimed that state law is displaced in its entirety because Congress has "occupied the field." A presumption against preemption is appropriate in such cases because it is consistent with basic tenets of federalism and of limited congressional powers. However, such a presumption has no place in cases of express preemption, where the central issue is whether particular

statutory or regulatory requirements enacted or authorized by Congress should be understood to displace state law. In such cases, the question of preemption is merely a question of straightforward statutory construction, and there should be no freestanding presumption that Congress has exercised its enumerated powers in any manner other than that which is most consistent with the plain meaning and effect of the specific preemptive provisions at issue. And, of course, with respect to implied conflict preemption, a conflicting state law is preempted by direct operation of the Supremacy Clause, and there is no presumption against the application of the Supremacy Clause.

ARGUMENT

I. THE FDCA'S EXPRESS PREEMPTION CLAUSE APPLIES TO "REQUIREMENTS" IMPOSED BY STATE COMMON LAW AS WELL AS THOSE IMPOSED BY STATE LEGISLATIVE AND REGULATORY ENACTMENTS.

The express preemption clause in the FDCA prohibits each state from "establish[ing] or continu[ing] in effect" any "requirement" that is "different from, or in addition to, any requirement" that the FDCA applies to the same medical device, and which relates to its safety, effectiveness, or any other matter governed by federal law. 21 U.S.C. § 360k(a). The Lohrs contend that "requirement[s]" means "only positive state law, not common-law tort claims," Lohrs' Br. at 17, and therefore that *all* common law damages actions -- regardless of whether they set requirements or standards that differ from a federal requirement that is directly applicable -- are immune from a claim-by-claim determination of whether they are preempted under section 360k(a). This extreme position is plainly wrong for a number of reasons.

First, in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), the Court rejected the very argument advanced by the Lohrs, holding that the inclusion of the term "requirements" in

an express preemption provision plainly covers requirements set by common law damages actions. In *Cipollone*, the Court was obliged to construe the express preemption provisions contained in two successive federal statutes -- the Federal Cigarette Labeling and Advertising Act, Pub. L. 89-92, 79 Stat. 282 (1965), and the Public Health Cigarette Smoking Act of 1969, Pub. L. 91-222, 84 Stat. 87 (1969). The Court determined that in the preemption provision in the 1965 Act, "Congress spoke precisely and narrowly: 'No statement relating to smoking and health shall be required in the advertising of [properly labeled] cigarettes.'" *Cipollone*, 505 U.S. at 518 (quoting section 5(b) of the 1965 Act). The Court noted that this language was consistent with "the continued vitality of state common law damages actions," and thus was "best read as having superseded only positive enactments by legislatures or administrative agencies that mandate particular warning labels." *Id.* at 518-19.

The Court held, however, that Congress changed the situation dramatically by enacting the "much broader" express preemption clause contained in the 1969 Act. 505 U.S. at 520. That provision introduced new constraints upon all manner of requirements, duties, and standards imposed under state law by stating that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes" that are labeled as required under federal law. 15 U.S.C. § 1334(b). Based on this language -- particularly the reference to "requirement[s] or prohibition[s] . . . imposed under State law" -- the Court held that common law actions were within the coverage of the express preemption provision contained in the 1969 Act. 505 U.S. at 520-24.[3]

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[3] The plurality opinion on this point actually speaks for the majority, for it is reinforced by the express agreement of Justices Scalia and Thomas. *See* 505 U.S. at 548-49 (Scalia, J., concurring and dissenting in part).

In *Cipollone*, the Court specifically rejected the Lohrs' linguistic argument designed to limit the scope of the term "requirement" to exclude the effects of damage actions brought under state common law. The Court explicitly found this argument to be "at odds both with the plain words of the 1969 Act and with the general understanding of common law damages actions." 505 U.S. at 521. In a key passage that squarely defeats the Lohrs' contentions to the contrary in this case, the Court stated: "The phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common law rules." *Id.* Even though there was some evidence in the legislative history suggesting that Congress "was primarily concerned with positive enactments by States and localities," the Court was emphatic that "the language of the Act *plainly* reaches beyond such enactments." *Id.* (emphasis added).[4]

Second, even if the Lohrs' argument were not squarely foreclosed by *Cipollone*, it is still plainly wrong because it ignores the ordinary interrelations between the substantive principles of the common law and statutory law in regulating the health, safety, and welfare of citizens in each state. Again, the Court discussed this point in *Cipollone*, and pointed out that "common law damage actions of the sort raised by petitioner are premised on the existence of a legal duty and it is difficult to say that such actions do not impose 'requirements or prohibitions,'" for "it is the essence of the common law to enforce duties that are either affirmative requirements or negative prohibitions." 505 U.S. at 522.

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[4] In Justice Scalia's separate opinion, which was joined by Justice Thomas, he expressly agreed that the broader language of the 1969 Act "plainly reaches beyond [positive] enactments," and that "general tort-law duties" can impose requirements or prohibitions within the meaning of the 1969 Act. *See* 505 U.S. at 548-49 (Scalia, J., concurring and dissenting in part).

In this regard, it simply does not matter whether the source of the substantive component of that state law is the state's legislature, regulatory agencies, or courts. It likewise does not matter whether the *remedy* used to enforce the substantive component of that law is the payment of damages to private parties rather than the payment of fines to the government or some other enforcement mechanism, and the Lohrs' arguments to the contrary, *see, e.g.*, Lohrs' Br. at 20, simply miss the mark. "[State] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." *San Diego Bldg. Trades Council, Millmen's Union, Local 2020 v. Garmon*, 359 U.S. 236, 247 (1959).

The intricate relationship between state common law and state statutory and administrative law in regulating private conduct, and the extent to which they are inherently interwoven, is well known and readily demonstrated. Earlier in this century, the courts typically led the way by applying and developing common law principles to regulate the private sector. The requirements, obligations, and standards imposed in accordance with these principles, in turn, were eventually codified and at times modified by state legislatures when they took the initiative to address particular problems and concerns. On occasion, legislatures have enacted regulatory statutes conferring administrative authority on government agencies to take more initiative in regulating private conduct, while still retaining the common law to fill many of the remaining gaps in coverage between these positive enactments. In many instances, the further interaction of state legislation and state common law adjudication becomes intricate and complex, with legislative or regulatory enactments sometimes used to supply the duty of care underlying private damage actions. *See generally* M. Eisenberg, *The Nature of the Common Law*, (1988); G. Calabresi, *A Common Law for the Age of Statutes* (1982).

At the state level, therefore, it is undeniable that the common law forms an integral, and interwoven, part of the comprehensive regulation of private conduct. Taken in combination with statutory and regulatory enactments, the common law imposes a continual procession of "requirements," obligations, prohibitions, and standards that are designed to influence and regulate the actions of businesses and individual citizens. Any reading of such terms to erect a putative distinction between the common law and positive law in this respect would be fundamentally misguided.

Third, the Lohrs' argument rests on the bizarre assumption that Congress intended that an *ad hoc* collection of state citizens assembled to hear one civil case -- a jury -- should have greater power to set standards that differ from uniform federal requirements than state officials acting through the careful, deliberative processes established in the legislative and administrative spheres. Such a result would be a perverse undermining of the democratic process. Moreover, the Lohrs' argument would suggest that the FDCA would preempt a state statute or administrative regulation imposing a $100 fine for engaging in particular conduct, but would not preempt a jury in state court from imposing a million-dollar damage award for engaging in the very same conduct. The Court should not assume that Congress intended such a strange result unless it clearly so provided. Nothing in the language of section 360k(a) requires that upside-down worldview. Indeed, for the reasons stated above, section 360k(a) plainly contemplates that state juries, just like state administrative and legislative officials, set "requirement[s]" that must be measured against federal action to determine if they are preempted.

Against all of this, the Lohrs offer only a far-fetched linguistic argument to support their assertion that state "requirements" includes only positive enactments and not those requirements imposed under state common law. They observe that the same term -- "requirement" -- is used in 21 U.S.C. § 360k(a) to refer *both* to federal requirements and to state

requirements. Yet because the federal "requirements" referred to are only those imposed by statute or administrative regulation (for there is no federal common law in this regard), they argue that the state "requirements" referenced must also be only those imposed by state statutes or regulations. Lohrs' Br. at 17-19.

This argument is untenable. The term "requirement" as used in 21 U.S.C. § 360k(a) refers to those prohibitions, standards, and obligations imposed *by law*, whether that law is state or federal. That there may be a variety of *sources* of law from which such requirements are derived, and that those sources of law may not mirror one another in every respect at the state and federal level is quite beside the point.

Indeed, the Lohrs' argument on this point is so plainly wrong that, if accepted here, its logic would partially overrule *Erie R.R. v. Tompkins*, 304 U.S. 64 (1938). The very same argument that the Lohrs put forward with respect to the use of the term "requirement" in section 360k(a) would apply equally well to the term "laws" in the Rules of Decision Act, 28 U.S.C. § 1652. The Rules of Decision Act requires a federal court to apply "[t]he laws of the several states" as the rules of decisions in civil actions not arising under federal law. Applying the logic of the Lohrs' argument, because the Supremacy Clause refers also to "the *Laws* of the United States," U.S. Const., art. VI, cl. 2 (emphasis added), and because there is no general common law of the United States, then the phrase "the laws of the several states" should be limited to the *positive* law of the several states, thereby excluding state common law as the governing rules of decision in federal courts. Adoption of the Lohrs' argument thus would have the pernicious consequence of upsetting the entire basis for the *Erie* doctrine.

It is, therefore, not surprising that, in *Cipollone*, the Court rejected the parallel argument that the phrase "State law" included *only* state statutes and regulations, but not state common law. *See* 505 U.S. at 522-23; *see also id.* at 549 (Scalia, J., concurring and dissenting in part) (agreeing that the

phrase "State law" used in the 1969 Act "embraces state common law"). The Court recognized that this argument was flatly irreconcilable with its longstanding construction of essentially the same language in the Rules of Decision Act. *See Erie*, 304 U.S. at 77-78. Indicating no desire to revisit the controversial battles fought over many decades that led up to the Court's historic decision in *Erie* to overrule the contrary interpretation of the Rules of Decision Act that had been adopted much earlier in *Swift v. Tyson*, 41 U.S. (16 Pet.) 1 (1842), the Court simply noted that "we have recognized the phrase 'state law' to include common law as well as statutes and regulations." *Cipollone*, 505 U.S. at 522. For all the same reasons, the Lohrs' attempt to limit the term "requirement[s]" to state positive law must fail.

II. THE ORDINARY PURPOSE OF A SAVINGS CLAUSE IS TO AVOID ANY INFERENCE OF "FIELD" PREEMPTION, AND IN ANY EVENT ITS GENERAL LANGUAGE DOES NOT CONTROL SPECIFIC PROVISIONS OF AN EXPRESS PREEMPTION CLAUSE.

The Medical Device Amendments ("MDA") to the FDCA also contain a so-called "savings clause" in section 360h(d). That section states that "[c]ompliance with an order [under the MDA] shall not relieve any person from liability under Federal or State law." *Id.* The Court of Appeals held that "[t]he existence of a savings clause within the MDA cannot alter th[e] conclusion" that the FDCA's express preemption provision covers state common law damages actions as well as state statutes and regulations. Pet. App. 12a. The Lohrs disagree, arguing that the existence of the savings clause in section 360h(d) "demonstrate[s] that the common law is beyond the reach of section 360k(a)," which is the express preemption clause. Lohrs' Br. at 12; *see also id.* at 27-28.

Once again, the Lohrs are mistaken. The most sensible reading of a savings clause like that in section 360h(d), especially in conjunction with an express preemption clause, is

that the savings clause is included merely to clarify that Congress disclaims any intention to preempt the common law *in its entirety* (*i.e.*, to "occupy the field"), but rather intends that preemption of common law claims should be determined on a claim-by-claim basis. The Lohrs' more extreme reading of the savings clause is incorrect for at least two reasons:

First, for the reasons already discussed, statutory terms denoting the scope of preemption, such as "requirements," "prohibitions," "standards," and "obligations," cannot be fairly read to include only positive enactments of law and not state common law. *See* Section I, *supra*. The Lohrs' reading of the savings clause would thus require the Court to restrict, and not respect, the plain meaning and reach of the broad terms Congress used in the express preemption clause.

Second, the Lohrs' suggestion that the existence of a savings clause should be read to immunize the common law from any possibility of express preemption would also lead to absurd consequences that Congress simply cannot be presumed to have intended. A simple example proves the point: Suppose that, in the course of approving a particular medical device to market under the FDCA's premarket approval application process, the FDA issues a regulation providing that the specific device at issue must be produced only with a certain component that is made of stainless steel, because stainless steel is more reliable and safer than other alternative materials. Is it conceivable that Congress could have meant its express prohibition of different state requirements not to reach a state common law damages action premised on the theory that the device was defectively designed because it was made of stainless steel instead of some other alternative material? Surely not. That would subordinate a specific federal decision to a conflicting state one. But that is the consequence of the Lohrs' argument that the existence of a savings clause somehow immunizes state common law from a claim-by-claim

determination of preemption under an express preemption clause.[5]

Amicus General Motors respectfully suggests that, rather than reading a savings clause as negating the plain meaning of an express preemption clause, thereby sanctioning an array of absurd results that Congress simply could not have intended, the Court should read the savings clause as merely clarifying that Congress did not intend to displace *all* state common law (*i.e.*, to occupy the field) by enacting the federal regulatory scheme, but rather intended that preemption of state common law should be determined on a claim-by-claim basis according to the terms of the express preemption clause.

This construction of the two provisions is consistent with the Court's prior cases, which have repeatedly held that a savings clause is merely meant to establish that Congress did not intend field preemption. *See, e.g., John Hancock Mut. Life Ins. Co. v. Harris Trust & Sav. Bank*, 114 S. Ct. 517, 526 (1993) (the consequence of a savings clause is that state law "generally is not displaced, but where [that] law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress, federal preemption occurs") (internal quotes omitted); *Pennsylvania R.R. v. Puritan Coal Mining Co.*, 237 U.S. 121, 130-32 (1915) (savings clause was included in Interstate Commerce Act to refute the claim "that, Congress having entered the field, the whole subject of liability of carrier to shippers in interstate commerce had been withdrawn from the jurisdiction of the state courts," without regard to whether any "administrative question" was posed under the federal law).

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[5] Of course, such a conflicting state requirement would be preempted by direct operation of the Supremacy Clause in any event, applying standard principles of implied conflict preemption. The case before the Court, however, has been litigated solely on grounds of express preemption. *See* note 2, *supra*.

The reading we suggest is also consistent with the Court's prior cases which have consistently held that the general language of a savings clause cannot control or limit the main thrust of an express preemption clause. *See, e.g., Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 385 (1992) ("general 'remedies' saving clause cannot be allowed to supersede the specific substantive pre-emption provision"). More generally, the Court has routinely given savings clauses a narrow reading in order to render them consistent with the preemptive thrust of the statute as a whole. *See, e.g., Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 51-52 (1987) (saving clause given narrow reading after the Court looked "to the provisions of the whole law, and to its object and policy").[6]

Thus, when Congress provides, as it often does, both that (i) any state requirement or standard that differs from an established federal requirement or standard is preempted, and that (ii) compliance with federal requirements is not meant to relieve a person of liability under the common law, the appropriate preemption inquiry with respect to a common law damages action is a claim-by-claim determination of the effect of allowing any such damages action to proceed. Where the common law damages action would have the effect of either setting a requirement or standard that differs from a federal

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[6] Indeed, even where the statute contains no express preemption clause at all, or where principles of implied conflict preemption are at issue, the general language of a savings clause cannot be read to save state common law claims that conflict with the overall purposes of the federal statutory scheme, which are preempted "by direct operation of the Supremacy Clause." *Brown v. Hotel & Restaurant Employees and Bartenders Int'l Union*, 468 U.S. 491, 501 (1984); *see also International Paper Co. v. Ouellette*, 479 U.S. 481, 493-94 (1987) (saving clause given narrow reading because "we do not believe Congress intended to undermine this carefully drawn statute through a general saving clause"); *Texas & Pacific Ry. Co. v. Abilene Cotton Oil Co.*, 204 U.S. 426, 446 (1907) (saving clause "cannot in reason be construed as continuing in shippers a common-law right, the continued existence of which would be absolutely inconsistent with the provisions of the act. In other words, the act cannot be held to destroy itself.").

requirement or standard already in place (express preemption) or otherwise conflicting with or undermining the main thrust of the federal statutory or regulatory scheme (implied preemption), *then and then alone* should the courts hold it to be preempted.

This approach -- which is essentially that followed by the Court of Appeals in this case -- rejects the polar extremes of either immunizing state law entirely from preemption or automatically displacing it in its entirety. Rather, this sensible approach would preempt state common law damages claims *only* to the extent that the effect of such claims would be to impose a requirement or set a standard that differs from a requirement or standard that is already in place under federal law. Accordingly, preemption of state common law claims would depend, in large part, on the specific action taken by the agency charged with enforcing the applicable federal statutory scheme. Only where Congress or the agency has imposed a federal requirement or standard will the state common law be prevented from operating in such a fashion as to impose a different requirement or standard. And determination of the preemptive effects of a particular federal requirement imposed by statute or regulation must be determined by the courts, to whom the authority is delegated to make such determinations in applying the Supremacy Clause. *Cf. Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649-50 (1990) (determination of whether a statute affords a private right of action is matter to be established by the judiciary rather than the implementing agency).

This is, we suggest, exactly how preemption should be understood to operate in the modern administrative state in areas of dual federal-state regulation. In enacting the general statutory scheme, Congress cannot know for sure exactly which state laws, requirements or standards should be preempted where Congress leaves it to the relevant federal administrative agency to determine which federal regulations to establish. Thus, Congress usually enacts a general provision (in an

express preemption clause) that state laws which differ from federal "requirements" or "standards" -- whatever they may turn out to be -- will be preempted, but also provides (in a savings clause) that the mere enactment of the federal law should not be understood to displace state law in its entirety. State law is thus neither completely immunized nor totally displaced. Rather, the scope of federal preemption will turn in large measure on what the federal agency does in implementing the statute. If the agency decides to issue a federal regulation to govern some aspect of the performance of the product at issue, then different state requirements or standards as to that same aspect of performance -- whether they be imposed through statutory or common law -- are preempted. But otherwise, state statutory and common law can continue to operate in the same realm alongside federal law, provided they do not otherwise conflict with or undermine the federal regulatory scheme.

In short, we respectfully suggest that the Court should avail itself of the opportunity in this case to reject explicitly the Lohrs' extreme position that the mere existence of a savings clause "demonstrates that the common law is beyond the reach of [an express preemption clause such as] section 360k(a)," Lohrs' Br. at 12, where the plain terms of that express preemption clause are broad enough to cover state common law. Instead, the Court should reiterate that a savings clause should be read in harmony with an express preemption clause, not in derogation of it.

III. PREEMPTION ISSUES ARE MATTERS OF PURE STATUTORY CONSTRUCTION AND THUS ARE NOT GOVERNED BY THE ESTABLISHED PRESUMPTION AGAINST "OCCUPY THE FIELD" PREEMPTION.

Finally, in conducting its claim-by-claim determination of whether the Lohrs' common law claims were preempted, the Court of Appeals expressly held that "in a close case the

presumptions [against preemption] tip our statutory interpretation against preemption." Pet. App. 9a.

Amicus General Motors respectfully suggests that the Court of Appeals was wrong to rely in any way on a purported presumption against preemption in a case, such as this one, that does not involve field preemption. Rather, in our view, this Court's prior statements concerning a presumption against preemption should be read to express its appropriate reluctance to infer that federal law has entirely "occupied the field" and thus is intended to displace *all* state law in a particular area. To the extent that the lower courts, such as the Court of Appeals in this case, have interpreted this Court's prior cases as endorsing a presumption against enforcing the statutory instructions about preemption contained in an express preemption clause, we believe they have erred. The Court should therefore clarify in this case that such a presumption has no place in interpreting the scope of an express preemption clause, or the effect of any other federal statute or regulation that, by its own terms, expressly displaces state law.

The first several cases in which the Court discussed a presumption against preemption were all cases that addressed "field preemption." *See, e.g., Reid v. Colorado*, 187 U.S. 137 (1902); *Savage v. Jones*, 225 U.S. 501 (1912); *Napier v. Atlantic Coast Line R.R.*, 272 U.S. 605 (1926). In such cases, the preemption issue turned on whether Congress intended for federal action to occupy an entire field of regulatory authority, thus ousting the states from exercising any police power at all in that same area. In the circumstances of such a claim, a general presumption against any such sweeping federal displacement of state law is indeed compatible with basic tenets of federalism, because it limits the displacement of state governmental authority based on generalized inferences that

are not anchored in any specific statutory language. *See, e.g., Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).[7]

Putting the settled principle of a presumption against broad "field" preemption to one side, however, the same considerations do not come into play in those cases where preemption issues are framed more narrowly by the comparison of express statutory or regulatory language contained in federal law to specific requirements, obligations, or standards imposed under state law. In such cases, these difficult preemption issues are quintessentially matters of statutory interpretation, which thus are not properly subject to any presumptions at all. *See, e.g., English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990); *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978); *cf. Cipollone*, 505 U.S. at 545 (Scalia, J., concurring and dissenting in part) ("The ultimate question in each case, as we have framed the inquiry, is one of Congress' intent, as revealed by the text, structure, purposes, and subject matter of the statutes involved.").

It is important to recognize that the preemption issues raised by particular statutes do not raise any *constitutional* questions about whether federal law can or should displace state law, for any such questions are directly answered by the terms of the Supremacy Clause. There is, quite simply, no presumption against Congress' explicit exercise of its enumerated powers. Thus, preemption issues involving the construction and application of particular statutes or regulations -- as opposed to the more generalized issue of whether Congress has intended to "occupy the field" and thus eliminate *all* state regulatory power -- do not afford the proper occasion for invoking any constitutional presumption against

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[7] It is also particularly inappropriate for the courts to invoke cases involving constitutional "clear statement" rules, such as *Gregory v. Ashcroft*, 501 U.S. 452 (1991) (Tenth Amendment), and *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234 (1985) (Eleventh Amendment), as supposed authority for such a presumption against preemption in ordinary statutory or regulatory cases.

the displacement of particular aspects of state law by the provisions of federal law. *Cf. Cipollone*, 505 U.S. at 545 (Scalia, J., concurring and dissenting in part) (any preliminary presumption "dissolves once there is conclusive evidence of intent to pre-empt in the express words of the statute itself, and the only remaining question is what the scope of that pre-emption is meant to be"). Instead, the proper rule of construction once again should be grounded in the basic "assumption that the ordinary meaning of [the statutory] language accurately expresses the legislative purpose." *Morales*, 504 U.S. at 383 (quoting *FMC Corp. v. Holliday*, 498 U.S. 52, 57 (1990)).

It is particularly important for the Court to make clear to the lower courts that any presumption against preemption is limited to so-called "field" preemption, but does not otherwise apply to limit the plain and natural scope of an express preemption clause.[8] The dangers in speaking in terms of overarching "presumptions" are perhaps not evident in the Court's own decisions, where it is recognized that the proper resolution of preemption issues requires carefully working through all of the relevant statutory and regulatory language before reaching a conclusion. In the lower courts, however, casual invocation of supposed "presumptions" at times becomes a substitute for hard legal analysis. *Compare Tebbetts v. Ford Motor Co.*, 665 A.2d 345, 346-48 (N.H. 1995) (invoking presumption to justify finding of no express preemption, and deducing from that an intention to foreclose implied conflict preemption analysis), *cert. denied*, 116 S. Ct. 773, *reh'g denied*, 1996 WL 77746 (1996) *with Freightliner Corp. v. Myrick*, 115 S. Ct. 1483 (1995) (applying plain

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[8] And, of course, with respect to implied conflict preemption, presumptions are utterly irrelevant because whenever state law conflicts with a federal statute or regulation, the conflicting state requirement is preempted "by direct operation of the Supremacy Clause." *Brown*, 468 U.S. at 501; *see also Cipollone*, 505 U.S. at 516 ("state law that conflicts with federal law is without effect").

language of preemption clause with no presumption, and then undertaking implied conflict preemption analysis). In this manner, the intended thumb on the scale often is transformed into a much more substantial weight, which exerts a disproportionate influence that skews or even short-circuits any meaningful judicial inquiry directed at the proper objective of divining congressional intent.

CONCLUSION

For the foregoing reasons, as well as those set forth in petitioner's brief, the decision below should be reversed in part and the case remanded for further proceedings in accordance with this Court's opinion.

Respectfully submitted,

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